SEP - 9 2003

K022752

HDC Corporation's Pandin Continuous Nerve Stimulating Catheter 510(k) Summary

Name of Device: Pandin Continuous Nerve Stimulating Catheter

Common or Usual Name: Continuous Nerve Stimulating Catheter

Classification Name: Kit, Conduction Anesthetic

CFR Section: 868.5140

Product Codes: CAZ

Submitter:

HDC Corporation
628 Gibraltar Court
Milpitas, CA 95035

Phone: (408) 942-7340
Facsimile: (408) 586-8680
Contact Person: Earl Smart
Date Prepared: 08\06\02
Predicate Devices:

Arrow International	HDC Corporation	HDC Corporation
StimuCath Continuous Nerve Block Set	CLA Kit (Nerve Block Infusion)	Neurotrac (Neuro-Trace)
K021567	K994059	K831715

Intended Use:

The Pandin Continuous Nerve Stimulating Catheter permits placement of catheters next to nerves and nerve plexus for continuous nerve block anesthesia or analgesia techniques. It is indicated for use up to 72 hours.

Substantial Equivalence:

All predicate devices presented for comparison with the Pandin™ Continuous Nerve Stimulating Catheter are single patient, single use, intended to facilitate the placement of a Peripherally Inserted Conductive Catheter for regional nerve block procedures. Additionally the Pandin™ Continuous Nerve Stimulating Catheter is used procedurally the same as the StimuCath™ (K021567) and contains the identical Tuhoy needle used in the CLA™ kit (K994059).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2003

Mr. Earl Smart
Quality Assurance Manager
HDC Corporation
628 Gibraltar Court
Milpitas, California 95035

Re: K022752
Trade Name: Pandin Continuous Nerve Stimulating Catheter
Regulation Number: 868.5140
Regulation Name: Kit, Conduction Anesthetic
Regulatory Class: II
Product Code: CAZ
Dated: June 12, 2003
Received: June 13, 2003

Dear Mr. Smart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K022752

Device Name Pandin Continuous Nerve Stimulating Catheter

Indications for Use The Pandin™ Continuous Nerve Stimulating Catheter permits placement of catheters next to nerves and nerve plexus for continuous nerve block anesthesia or analgesia techniques. It is indicated for use up to 72 hours.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-tne-counter Use _____
(Per 21 CFR 801.109)

9/4/03 for JXH 9/4/03
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022752